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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,479	03/09/2004	Lou Tateo	TYHC:0148/FLE (P0428T)	3288
52144	7590	08/24/2005	EXAMINER	
FLETCHER YODER (TYCO INTERNATIONAL, LTD.)			BUNIN, ANDREW M	
P.O. BOX 692289			ART UNIT	
HOUSTON, TX 77269-2289			PAPER NUMBER	

3743

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary

Application No.

10/797,479

Applicant(s)

TATEO ET AL.

Examiner

Andrew M. Bunin

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the protrusions (flexible flap) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brain (US 5878745) in view of Pagan (US 6003514). Brain discloses a laryngeal airway device, comprising an airway tube 11 having a proximal end and a distal end, said airway tube having an internal passage in the airway tube wall as shown in Figure 1. In addition, Brain discloses a dome 13 having an inlet and an outlet, said dome connected at its inlet with said distal end of said airway tube; an annular spoon-shaped inflatable cuff 18 connected with the periphery of said outlet of said dome; a cuff inflation line 19 having a proximal end and a distal end, wherein said cuff inflation line 19 is configured to be in fluid communication with the internal space of said cuff; and an aperture 14 having multiple lobes formed in said dome; said aperture configured to be in fluid communication with the proximal end of said airway tube. A lobe is defined as a "rounded projection" (dictionary.com). Therefore, the top and bottom rounded sections of 14 can each be defined as separate lobes of the aperture. However, Brain doesn't explicitly disclose the dome as having a plurality of protrusions forming said aperture, and wherein one of said protrusions is configured to prevent the obstruction of said aperture by a patient's epiglottis. Pagan discloses a laryngeal airway device with an aperture having multiple lobes (34 and 35) and a plurality of protrusions (31 and 32)

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forming said aperture, and wherein one of said protrusions is configured to prevent the obstruction of said aperture by a patient's epiglottis (column 1, lines 34-38). Pagan continues to teach the protrusions 31/32 comprising a flexible flap. Therefore, it would have been obvious to a person with ordinary skill in the art at the time of the invention to modify Brain with the protrusions taught by Pagan in order to deflect the epiglottis during the insertion of an airway device into patient thereby preventing the epiglottis from entering the air passage.

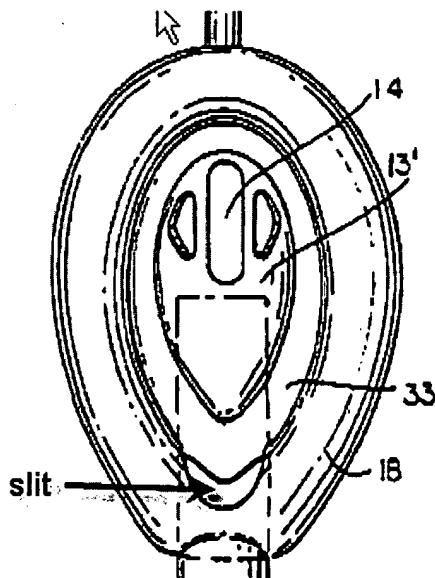
As for claim 3, Brain and Pagan disclose everything except the other of said protrusions are less flexible than said one of said protrusions. However, Applicant's specification does not set forth this feature, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

As for claim 4, Brain and Pagan disclose everything except that one of said protrusions is larger than the other of said protrusions. However, Applicant's specification does not set forth this feature, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

As for claim 5, Brain discloses a device with an elongated lobe. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add another elongated lobe, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

As for claim 6, Brain discloses a protruding dome tip 40 connected with the distal end of said outlet of said dome 13, said protruding dome tip's distal end being located in and in fluid communication with said internal space of said cuff 18 as shown in Figure 3.

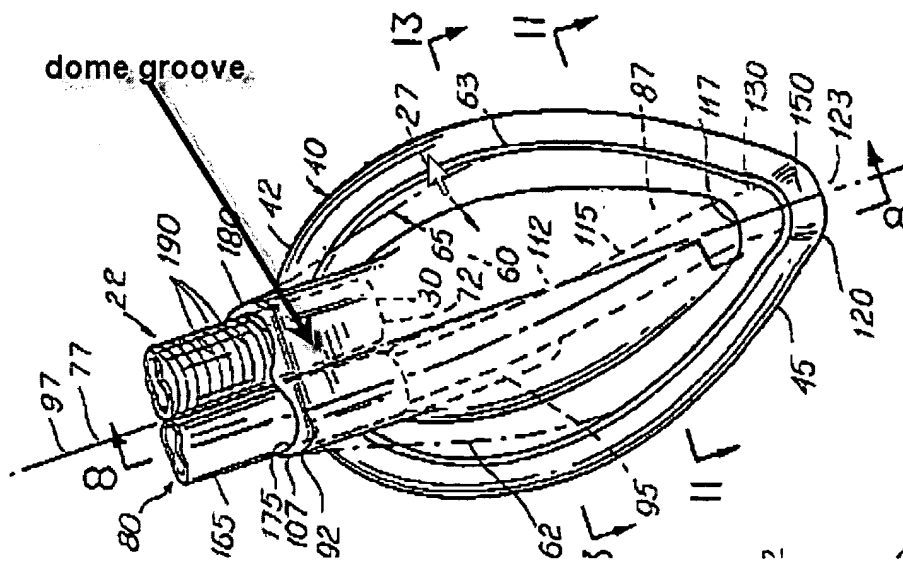
As for claim 14, the protruding dome tip 40 comprises a slit at its distal end, so as to cause said protruding dome tip to maintain fluid communication with the internal space of said cuff 18 when said cuff is adjacent to said distal end of said protruding dome tip 40 (see Figure 3 and Figure below).



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As for claim 15, Brain discloses the protruding dome tip 40 which is part of the dome 13 is less elastic than the cuff 18 so as to prevent said cuff from folding back on itself when said device is inserted into a patient (column 4, lines 1-18).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brain and Pagan in view of Brain (US 6439232). Brain and Pagan have taught everything except the dome further comprising a groove and wherein said cuff inflation line is configured to fit in said groove. However, US 6439232 has taught a laryngeal airway device with a cuff 40 and a dome 27 comprising a groove wherein said cuff inflation line is configured to fit in said groove as shown in Figures 3 and 7 (see Figure below).



US 6439232 (Prior Art)

Claims 8-10, 16, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brain in view of Pagan.

Brain discloses the outlet of the dome further comprising a tray portion 33, and said cuff 18 further comprises a channel on the inner surface of the annular shaped cuff, said channel 38 being connected with the periphery of said outlet of said dome at said tray portion 33 (Figure 4).

Brain continues to disclose the cuff's outer surface as being formed in the absence of external protrusions, said cuff 18 further comprising a mold extraction orifice 27 at its distal end formed on an internal surface of said cuff, and wherein said cuff inflation line 19 is configured to be in fluid communication with the internal space of said cuff at an opening comprising said mold extraction orifice as shown in Figures 1 and 2. Although Brain and Pagan haven't explicitly taught a removable connector connected with said proximal end of said airway tube. Applicant has disclosed prior art in Figure 1 of the Specification that teaches the connector 7 as claimed.

Claims 11, 12, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brain and Pagan in view of Neame et al. (US 5979445).

Brain discloses a cuff inflation line 19 that is configured to be in fluid communication with the internal space of said cuff 18 at a distal end of said cuff. However, Brain and Pagan don't explicitly disclose an inflation line insertion point offset distally from said proximal end of said airway tube, said insertion point being the proximal end and integral with said internal passage. However, Neame et al. teach a laryngeal device with an inflation line insertion point (where 3 meets 1) offset distally from said proximal end of said airway tube 1, said insertion point being the proximal end

and integral 2 with said internal passage. A portion of the length of said cuff inflation line 2 is placed in said passage 1 as shown in Figure 1.


Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 5896858, US 6390093, US 6240922, US 4509514, US 5584290, US 6895966, and US 5850832

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Bunin whose telephone number is (571)272-4801. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


AMB
8/11/05


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